A2. 510(k) Summary

MAY 16 2013

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: k124040

1. Submitter Information:

Application Correspondence:
Contact Person: Pinjung Chen
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Date of submission: Dec 21, 2012

Applicant (the 510(k) Owner):
Company Name: FORA Care Inc.
Contact Person: Sophia Wu
Address: 810 Lawrence Drive, Suite104, Newbury Park, CA 91320
Phone: (805) 498-8188
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2. Device name:

Proprietary name: ForaCare GD20 Blood Glucose Monitoring System

Regulatory information:

A. Regulation section: 21 CFR 862.1345 Glucose Test System
B. Classification: Class II
C. Product Code: LFR, Glucose Dehydrogenase, Glucose
NBW, System, Test, Blood Glucose, Over The Counter

D. Panel: Chemistry (75)

3. Intended Use:

The ForaCare GD20 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples (from the finger, palm, forearm and upper arm,). It is intended for use by a single person and should not be shared.

The ForaCare GD20 Blood Glucose Monitoring System is intended for self-testing use outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes, or for testing of neonates. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The ForaCare GD20 test strips are for use with the ForaCare GD20 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm and upper arm.

4. Device Description:

The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results.

Substantial Equivalence Information:

A. Predicate device name: U-RIGHT TD-4252 Blood Glucose Monitoring System, model TD-4252
B. Predicate K number: K101631
C. Comparison with predicate:

The modified **ForaCare GD20 Blood Glucose Monitoring System** has the following similarities to the predicate device:

- Same operating principle.
- Same fundamental scientific technology.
- Incorporate the same basic circuit design.

- Incorporate the same materials.
- Same shelf life.
- Packaged using the same materials.
- Manufactured by the same process.

The modifications encompass:

- Physical appearance change,
- Data transmission function with RS232
- Fix measurement unit to mg/dL
- Labeling change due to the above modifications.

5. Test Principle:
   The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose dehydrogenase.

6. Performance Characteristics:
   ForaCare GD20 Blood Glucose Monitoring has the same performance characteristics as the predicate device.

   1) Comparison System Accuracy and Precision

   The comparison of system accuracy performance and precision test demonstrate that the ForaCare GD20 Blood Glucose Monitoring System and U-RIGHT TD-4252 Blood Glucose Monitoring System are substantially equivalent.

   2) Clinical Accuracy study with capillary blood from the fingertip

   ForaCare GD20 Blood Glucose Monitoring System met the minimum acceptable accuracy required by EN ISO 15197 and recommendation of FDA guidance.

   3) Consumer Performance Study

   ForaCare GD20 Blood Glucose Monitoring System met the minimum acceptable accuracy required by EN ISO 15197 and recommendation of FDA guidance.

   4) Human Factors Study of the Data Transmission Feature

   The study demonstrates the usability of the data transmission feature and the Fora Health Care System software is easy for lay users in the homecare environment.

   5) Bench Testing of the Data Transmission Accuracy

   The bench testing demonstrates accuracy (100%) of data transmission from ForaCare GD20 Blood Glucose Monitoring System to Fora Health Care System software.

   6) Software Validation Test

Software verification and validation testing confirmed that the performance, safety and effectiveness of ForaCare GD20 Blood Glucose Monitoring System are equivalent to the predicate device.

7) Cleaning and Disinfection Validation Test

The cleaning and disinfection protocol employed by the systems is validated for the effectiveness of disinfecting HBV, and are robust to cleaning and disinfection procedures after multiple cleaning and disinfection cycles.

7. Conclusion:

Analytical performance testing on the ForaCare GD20 Blood Glucose Monitoring System demonstrated that the device meets the performance requirement for its intended use. The usability testing and data transmission study showed the modified features of the proposed device are safe for intended use for the users. The data demonstrates that ForaCare GD20 Blood Glucose Monitoring System is substantially equivalent to the predicate U-RIGHT TD-4252 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2013

Taidoc Technology Corp.
C/O Pinjung Chen
6F, NO. 127, WUGONG 2ND RD, WUGU DISTRICT
NEW TAIPEI CITY, 24888, TAIWAN

Re: K124040
Trade/Device Name: ForaCare GD20 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: LFR, NBW
Dated: April 15, 2013
Received: April 18, 2013

Dear Pinjung Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

A3. Indications for Use Form

Indications for Use Form

510(k) Number (if known): **k124040**

Device Name: **ForaCare GD20 Blood Glucose Monitoring System**

Indications for Use:

The ForaCare GD20 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples (from the finger, palm, forearm and upper arm,). It is intended for use by a single person and should not be shared.

The ForaCare GD20 Blood Glucose Monitoring System is intended for self-testing use outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes, or for testing of neonates. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The ForaCare GD20 test strips are for use with the ForaCare GD20 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm and upper arm.

Prescription Use _____ AND/OR Over the Counter Use __X__
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostics and Radiologic Health
510(k) k124040